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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,869	12/09/2003	Carl D. Wahlstrand	1023-318US01	6690
28863	7590	02/23/2006	EXAMINER	
SHUMAKER & SIEFFERT, P. A. 8425 SEASONS PARKWAY SUITE 105 ST. PAUL, MN 55125			ALTER, ALYSSA M	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/731,869

Applicant(s)

WAHLSTRAND ET AL.

Examiner

Alyssa M. Alter

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-31 and 33-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-31 and 33-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/3/06.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Response to Arguments*

Applicant's arguments with respect to claims 1-57 have been considered but are moot in view of the new ground(s) of rejection in view of Meltzer (US 5,645,586).

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

1. Claims 1-31 and 33-57 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/731,638 (US Patent Publication 20040176817 A1).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 2, 11, 13-17, 19-23, 33-34, 36-42 and 51-55 are rejected under 35 U.S.C. §102(b) as being anticipated by Meltzer (US 5,645,586). Meltzer discloses an implantable defibrillator with a flexible housing that surrounds a flex-circuit assembly as seen in figure 5. The logic assembly 56 is considered to be the first module and the battery 55 is considered to be the second module. The overmold is the flexible housing 50 and 51. Since the circuit and housing are flexible they can be manipulated and deformed in a plurality of degrees of freedom.

As to claim 15, "the assembly may be packed in a non-toxic foam or other padding, or it may be slightly filled with an inert fluid, to cushion the internal components of the device"(col. 4, lines 60-63). Therefore, the overmold comprises at least two materials, the housing and the inert fluid for cushioning.

As to claims 16-17, 23, 33, 40, 42 and 51, the flexible interconnect member is the flexible flex-circuit assembly 52. As stated above the flexible circuit can be manipulated and deformed in a plurality of degrees of freedom.

As to claims 19, 36 and 52, the lead 59, lead connector 58 and connector port 57 can be seen in figure 5.

As to claims 21 and 53, the functional language and introductory statement of intended use of claim(s) 21 and 53 have been carefully considered but are not considered to impart any further structural limitations over the prior art. Since Meltzer utilizes an implantable medical device as claimed by the Applicant, Meltzer is therefore capable of being implanted on the cranium. In addition nothing prevents Meltzer from implanting the implantable medical device in the cranium. Therefore, the implantable medical device as taught by Meltzer is shaped for implantation on the cranium.

As to claim 55, the battery and/or capacitors are considered to function as the pulse generator by delivering pulses or therapy to the patient.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 18 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meltzer (US 5,645,586). Meltzer discloses the claimed invention except for the cylindrical modules. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the shape of the modules as taught by Meltzer with a cylindrical modules since it was known in the art to modify medical devices components to yield smaller and lighter implantable devices.

2. Claims 3-10, 12, 24-31, 43-50 and 56-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meltzer (US 5,645,586) in view of Munshi et al. (US 5,411,537). Meltzer discloses the claimed invention except for the rechargeable battery and coil. Munshi et al. teaches that it is known to utilize a rechargeable battery for an implantable medical device for the purpose of making the implantable device smaller and lighter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the battery as taught by Meltzer with the rechargeable battery and coil as taught by Munshi et al. in order to eliminate removal of an implantable medical device when the battery is expired. Recharging a battery prevents explantation and re-implantation when the battery is changed.

As to claims 5-9, 26-30, 45-49 the modified Meltzer discloses the claimed invention except for location of the recharge coil. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the location of the recharge coil, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70 (see MPEP 2144.04). Therefore, to create a coil within the overmold or outside of the overmold is merely a rearranging of parts.

As to claim 12, when the implantable medical device is implanted on the cranium there is obviously a portion of the device will be proximate to the cranium of the patient.

As to claims 10, 31, 50 and 57, the modified Meltzer discloses the claimed invention but does not disclose expressly the helix as the flexible tether. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify

the modules location as taught by the modified Meltzer, with the helix tether, because Applicant has not disclosed the helix tether provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with a non-helix tether, since both types of tethers would join the medical device.

Therefore, it would have been an obvious matter of design choice to modify the tether to obtain the invention as specified in the claim(s).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

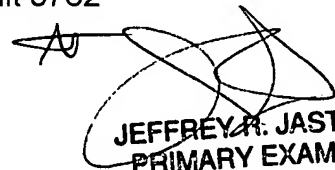
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alyssa M Alter  
Examiner  
Art Unit 3762



JEFFREY R. JASTRZAB  
PRIMARY EXAMINER  
2/16/06